REMARKS

The Examiner is thanked for the due consideration given the application. The specification has been amended to insert priority information and to improve the headings.

Claims 1-12 are pending in the application. Claims 13-16 have been canceled without prejudice or disclaimer. The clams have been amended to improve their language in what is believed to be a non-narrowing fashion.

The Specification

The specification has been objected to as not containing priority information. The specification has been amended to contain priority information.

Claim Objections

Claim 8 has been objected to as containing informalities. Claim 8 has been amended to be free from informalities.

Rejection Under 35 USC §101

Claim 13 has been rejected under 35 USC §101 as being a non-statutory "use" claim. This rejection is respectfully traversed.

Claim 13 has been canceled by this amendment, thereby rendering this rejection moot.

This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

Rejection Under 35 USC §112, Second Paragraph

Claims 1-16 have been rejected under 35 USC §112, second paragraph. This rejection is respectfully traversed.

The comments in the Official Action have been considered, and the claims have been amended accordingly.

However, regarding claim 1, it is noted that there is a difference between the limitation "b) low density lipoprotein (LDL) cholesterol relative to high density lipoprotein (HDL) cholesterol" and the limitation "c) low density lipoprotein (LDL) cholesterol." Limitation "c" clearly pertains to the absolute level of LDL cholesterol. However limitation "b" pertains to the level of LDL cholesterol compared to the level of HDL cholesterol.

For example, if both the HDL cholesterol and LDL cholesterol are each reduced by 50%, limitation "c" may be fulfilled while limitation "b" may not be fulfilled. On the other hand, if the LDL cholesterol is reduced 60% while the HDL cholesterol is reduced by 50%, then both the absolute and comparative conditions are fulfilled, and both limitations "b" and "c" are satisfied.

It would also be clear to one of skill in the art that elements "a" to "f" can be reduced simultaneously or in combination(s). It is noted that the conditions "a" to "f" are inter-related phenomena relating to blood serum.

The claims are thus clear, definite and have full antecedent basis.

This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

Rejections Under 35 USC §102

Claims 14-16 have been rejected under 35 USC §102(a) as being anticipated by BEALES et al. (2002 *Diabetalogia* 45(9): 1240-1246). Claims 13-16 have been rejected under 35 USC §102(e) as being anticipated by ELLIOTT et al. (U.S. Patent 6,451,638). This rejection is respectfully traversed.

Claims 13-16 have been canceled by this amendment, thereby rendering these rejections moot.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

Rejection Under 35 USC §103(a)

Claims 1-16 have been rejected under 35 USC §103(a) as being unpatentable over ELLIOTT et al. (WO 0100047). This rejection is respectfully traversed.

The present invention pertains to a method of reducing the serum levels in a mammal of at least one of a) cholesterol; b) low density lipoprotein (LDL) cholesterol relative to high density lipoprotein (HDL) cholesterol; c) low density lipoprotein (LDL) cholesterol; d) very low density lipoprotein (VLDL) cholesterol; e) apolipoprotein B; and f) triglycerides. The method of the present invention includes orally administering to a mammal

a composition comprising β-casein where the β-casein is comprised of at least 95% β-casein A^2.

ELLIOTT et al. describe a dietary supplement containing milk that is fortified by the addition of other components such as folic acid, and the effect of the fortified dietary supplement is said to be the reduction of plasma levels of homocysteine. A reduction of homocysteine levels is said to reduce the incidence of vascular disease, particularly cardiovascular disease and cerebrovascular disease. ELLIOTT et al. also discuss that diabetes causes vascular disease and that there "may be common ground" with homocysteine levels.

ELLIOTT et al. also discuss the correlation between the incidence of Type I diabetes and the consumption of β-casein variants A and B (through milk consumption). ELLIOTT et al. say that a dietary supplement fortified by a component such as folic acid and including milk or a milk product having a β-casein content which is substantially β-casein A^2 is capable of reducing vascular diseases. It is postulated that the reduction in vascular disease is caused both by reducing homocysteine levels and by reducing the incidence of diabetes. ELLIOTT et al. also postulate that β-casein A^2 is converted in the gut to a stable compound (β-casomorphin 9) which promotes immunity against diabetes.

ELLIOTT et al. discuss (see second paragraph on page 13) that the compositions are intended to reduce the incidence of

vascular disease and to reduce the incidence of diabetes. ELLIOTT et al. clearly says that the reduction of vascular disease is "directly through the use of tHcy reducing agents" and "indirectly by reducing the incidence of diabetes through (a) provision of bovine milks high in the A2 variant of beta-casein and low in Al and B variants, and/or (b) exploitation of the immunological properties of beta-casomorphin 9."

ELLIOTT et al. fail to teach or infer that serum levels of cholesterol, LDL cholesterol, VLDL cholesterol, apolipoprotein B, and trigycerides can be influenced by β-cassein A^2 or BCM, with the biological action of the latter described in ELLIOTT et al. as an immunomodulator.

All that is described in ELLIOTT et al., with respect to β-casein A^2, is that there is a correlation between the incidence of diabetes and β-casein A^1 and B. In other words, all that can be taken from ELLIOTT et al. is that the incidence of diabetes may be reduced by consuming food products (specifically milk) which do not have β-casein A^1 or B, which in effect means consuming milk and milk products containing β—casein A^2. There is no inference in ELLIOTT et al. that β—casein A^2 has a positive effect on the reduction of diabetes incidence.

Even if ELLIOTT et al. was interpreted as saying β-casein A^2 has a positive effect on the reduction of diabetes incidence, the only proposition taken from ELLIOTT et al. that can be put forward to explain that effect is that β—casomorphin 9

acts as an immunomodulator (see first paragraph on page 14). It is not possible to extrapolate from this and say that β–casein A^2 lowers serum levels of cholesterol, LDL cholesterol, VLDL cholesterol, apolipoprotein B and triglycerides. Indeed, ELLIOTT et al. teach away from this by indicating that the effect on diabetes is caused by β-casomorphin 9 and that this casein fragment has an effect on antibodies against beta-islet cells of the pancreas (see lines 402-405 on page 14).

In contrast, the claims of the present invention relate to methods for reducing serum levels of cholesterol, LDL cholesterol, VLDL cholesterol, apolipoprotein B, and triglycerides, and for treating related diseases such as hypercholesterolemia, hyperlipidemia, and atherosclerosis. This is based on the first known direct experimental evidence for the reduction of these components in rabbit serum by consumption of β-casein A^2 (see the Examples section).

The effect on these levels could not be predicted by a person skilled in the art simply from the disclosure of ELLIOTT et al. Vascular disease and diabetes have numerous contributing factors and physiological indicators. It is not possible, based on a reasonable scientific prediction, to say that the negative effect of β-caseins A^2 and B (or even the positive effect of β-casein A^2) on vascular disease and diabetes suggests a positive effect of β-casein A^2 on serum levels of cholesterol, LDL

cholesterol, VLDL cholesterol, apolipoprotein B, and triglycerides.

At page 7, the Official Action asserts that the elements of reducing cholesterol, apoliproprotein, triglycerides, hypercholesterolemia, hyperlipidemia and atherosclerosis would occur to one of ordinary skill in light of the single reference of ELLIOT. However, the Official Action fails to point out where in the single reference of ELLIOT itself a teaching or inference of these elements resides.

To establish a *prima facie* case of unpatentability, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." *MPEP* §2143. In addition, if a reference needs to be modified to achieve the claimed invention "there must be a showing of a suggestion or motivation to modify the teachings of that reference to the claimed invention in order to support the obviousness conclusion." *Sibia Neurosciences Inc. v. Cadus Pharmaceutical Corp.*, 225 F.3d 1349, 55 USPQ2d 1927 (Fed. Cir. 2000).

A person skilled in the art, knowing from ELLIOT et al. that there is a correlation between β-casein A^1 and cardiovascular disease, could not predict with any certainty the administration of β-casein A^2 would reduce serum levels of cholesterol, LDL cholesterol, VLDL cholesterol, apolipoprotein B, and triglycerides.

As a result, a *prima facie* case of unpatentability has not been made over independent claims 1 and 3. Claims depending upon claims 1 or 3 are patentable for at least the above reasons.

This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

Conclusion

The Examiner is thanked for considering the Information Disclosure Statements filed July 25, 2005 and July 5, 2005 and for making initialed PTO-1449 Forms of record in the application. The Examiner is respectfully requested to consider the Information Disclosure Statement filed October 24, 2007 and to make an initialed PTO-1449 Form of record in the application.

Prior art cited but not utilized is believed to be non-pertinent to the instant claims.

The objections and rejections are believed to have been overcome, obviated or rendered moot and that no issues remain. The Examiner is accordingly respectfully requested to place the application in condition for allowance and to issue a Notice of Allowability.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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